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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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| 09/404,979 | 09/22/1999 | T. VENKAT GOPAL | GENAPP.002RA | 8979 |

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| EXAMINER |
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MCKELVEY, TERRY ALAN

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| ART UNIT | PAPER NUMBER |
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1636

DATE MAILED: 07/14/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/404,979

Applicant(s)

GOPAL, T. VENKAT

Examiner

Terry A. McKelvey

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE TWO MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 14 April 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-14 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-14 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☒ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date 12/19/03; 4/7/04; and 3 4/14/04 LRS's
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 4/14/04 has been entered.

Information Disclosure Statement

The crossed-out portions of the information disclosure statements filed 12/19/03, 4/14/04 and 4/7/04 fail to comply with the provisions of 37 CFR 1.97, 1.98 and MPEP § 609 because either the citations are duplicates and thus already considered or are drawn to application numbers that although actually considered, were crossed-out because it is not appropriate to print application numbers on the face of the patent issuing from the instant application. It has been placed in the application file, but the information referred to therein has not been considered as to the merits except as described above.

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Reissue Applications

The reissue oath/declaration filed with this application is defective (see 37 CFR 1.175 and MPEP § 1414) because of the following:

The reissue declaration filed 5/17/2001 is incomplete in the instant application because page 1 is missing in the official file and thus the reissue declaration cannot be reviewed for compliance with the requirements for reissue declarations.

In accordance with 37 CFR 1.175(b)(1), a supplemental reissue oath/declaration under 37 CFR 1.175(b)(1) must be received before this reissue application can be allowed.

Claims 1-14 are rejected as being based upon a defective reissue declaration under 35 U.S.C. 251. See 37 CFR 1.175. The nature of the defect is set forth above.

Receipt of an appropriate supplemental oath/declaration under 37 CFR 1.175(b)(1) will overcome this rejection under 35 U.S.C. 251. An example of acceptable language to be used in the supplemental oath/declaration is as follows:

"Every error in the patent which was corrected in the present reissue application, and is not covered by a prior oath/declaration submitted in this application, arose without any deceptive intention on the part of the applicant."

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In the instant case, it is not clear whether the last reissue declaration, along with the other reissue declarations, covers all of the amendments to the specification and claims. Thus, applicants should take extra care to file a supplemental declaration that fully complies with the rules governing reissue oath/declarations. For example, in the originally filed reissue declaration, the third statement is "I have reviewed and understand the contents of the specification of the accompanying reissue declaration." It should have included the phrase "and claims as amended" after "specification" in order to encompass the amended claims. Every amendment to the specification and claims needs to be accounted for by the reissue declaration.

Specification

The disclosure is objected to because of the following informalities:

The amendment to the specification filed 9/7/2000, specifically, the amendment to the paper sequence listing correcting the sequence of SEQ ID NO:30, was not made as set forth in 37 CFR 1.173(b)(1) because the original sequence was not shown as being deleted by bracketing and the new sequence was not shown as being added by underlining.

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It should be noted that Applicant need not file a new CRF disk and sequence statement. The instantly required amendment (using the reissue amendment format) to the paper sequence listing does not and cannot be present in the same format in the CRF disk. The statement concerning the CRF and the paper sequence listing being the same is meant to be directed to the substance of the two sequence listings being the same and thus even with the different format of the amendment to the paper sequence listing being required, the substance is unchanged and thus the previously filed CRF and sequence statement are still applicable.

Also, the amendment filed 6/16/03 adding the continuity data was improperly made because the sentence/paragraph being added was not underlined as required.

The applicant must review the entire application to make sure that all amendments have been made using the reissue amendment rules, and correct additional improper amendments if any are present.

Appropriate correction is required.

Claim Objections

Claims 1-14 are objected to because of the following informalities:

The text of the last set of claims filed 1/30/2001 is of such poor quality that some of the letters in the words of the claims did not reproduce during the scanning process used to enter the amendment into the official electronic file of the application. For example, claim 2, line 2 "between" appears as "b tween"; claim 3, line 1, "vector" appears as "v ctor". Also, the inserted words are double-underlined instead of the single underlining required by 37 CFR 1.173(b)(2) and (d). Filing a new set of claims using the required reissue amendment rules, would be remedial. Appropriate correction is required.

Response to Applicant's Arguments and Amendment

The applicant's arguments drawn to the specific cited references in combination with the declaration filed 6/16/03 under 1.131 indirectly antedating the Woo et al and Smith et al references (essentially by showing that the differences between the claimed invention and the showing under 37 CFR 1.131 would have been obvious to one of ordinary skill in the art in view of applicant's 37 CFR 1.131 evidence) and the declaration filed on 4/14/2004 under 37 CFR 1.131 is sufficient to overcome the Woo et al and Smith et al references.

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Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1-7 and 9-12 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1, 3, and 5 of U.S. Patent No. 5,811,297. An obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but an examined application claim is not patentably distinct from the reference claim(s) because the examined claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985). Although the conflicting claims are not identical,

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they are not patentably distinct from each other because claims 1-7 and 9-12 are generic to all that is recited in claims 1, 3, and 5 of U.S. Patent No. 5,811,297. That is, the polypeptide part of the transfection vector of claims 1, 3, and 5 of U.S. Patent No. 5,811,297 falls entirely within the scope of claims 1-7 and 9-12 or, in other words, claims 1-7 and 9-12 are anticipated by claims 1, 3, and 5 of U.S. Patent No. 5,811,297. Specifically, the polypeptide portion of the transfection vector comprising a basic peptide segment, NLS, and a neutral hinge and specific polypeptide of claims 1, 3, and 5 of U.S. Patent No. 5,811,297 have the same or narrower scope than and is totally encompassed by the transfection vectors of claims 1-7 and 9-12 drawn to transfection vectors comprising the same elements and having specific limitations of the same scope or broader than the specific vector of claim 5 of U.S. Patent No. 5,811,297.

Conclusion

No claims are allowed.

Please specifically note, for this action in a reissue application, a shortened statutory period for reply to this action is set to expire TWO MONTHS from the mailing date of this action. Failure to respond within the period for response will cause the application to become abandoned. Also, any extensions

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of time must be requested in advance under the provisions of 37 CFR 1.136(b) only.

Certain papers related to this application may be submitted to Art Unit 1636 by facsimile transmission. The faxing of such papers must conform with the notices published in the Official Gazette, 1156 OG 61 (November 16, 1993) and 1157 OG 94 (December 28, 1993) (see 37 C.F.R. § 1.6(d)). The official fax telephone number for the Group is 703-872-9306. NOTE: If Applicant does submit a paper by fax, the original signed copy should be retained by applicant or applicant's representative. NO DUPLICATE COPIES SHOULD BE SUBMITTED so as to avoid the processing of duplicate papers in the Office.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to (571) 272-0547.

Patent applicants with problems or questions regarding electronic images that can be viewed in the Patent Application Information Retrieval system (PAIR) can now contact the USPTO's Patent Electronic Business Center (Patent EBC) for assistance. Representatives are available to answer your questions daily from 6 am to midnight (EST). The toll free number is (866) 217-9197. When calling please have your application serial or patent number, the type of document you are having an image problem

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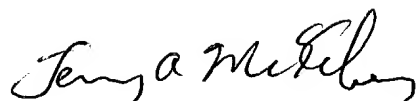
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For all other customer support, please call the USPTO Call Center (UCC) at 800-786-9199.

Any inquiry concerning rejections or objections in this communication or earlier communications from the examiner should be directed to Terry A. McKelvey whose telephone number is (571) 272-0775. The examiner can normally be reached on Monday through Friday, except for Wednesdays, from about 7:30 AM to about 6:00 PM. A phone message left at this number will be responded to as soon as possible (i.e., shortly after the examiner returns to his office).

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Dr. Remy Yucel can be reached at (571) 272-0781.



Terry A. McKelvey, Ph.D.
Primary Examiner
Art Unit 1636

July 12, 2004